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Datasheet for the decision of 2 October 2019

Case Number: T 0365/14 - 3.3.08

Application Number: 00946953.7

Publication Number: 1190043

IPC: C12N15/00, C07K14/00, C07K14/47, C07K16/18

Language of the proceedings: EN

Title of invention:
GLYCOPROTEIN VI AND USES THEREOF

Patent Proprietor:
MILLENNIUM PHARMACEUTICALS, INC.

Opponents:
SANOFI-AVENTIS DEUTSCHLAND GMBH
advanceCor GmbH

Headword:
GLYCOPROTEIN VI/MILLENNIUM PHARMACEUTICALS

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 80, 115(2)
RPBA Art. 15(3)

Keyword:
Main description request - Article 123(2) EPC (no)
Auxiliary description request not admitted

Decisions cited:
T 1149/97

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 0365/14 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 2 October 2019

Appellant: (Patent Proprietor)	MILLENNIUM PHARMACEUTICALS, INC. 75 Sidney Street Cambridge, Massachusetts 02139 (US)
Representative:	Bourgarel, Denis Cabinet Plasseraud 235 Cours Lafayette 69006 Lyon (FR)
Appellant: (Opponent 2)	advanceCor GmbH Fraunhoferstrasse 17 82152 Planegg (DE)
Representative:	Blodig, Wolfgang Wächtershäuser & Hartz Patentanwaltspartnerschaft mbB Weinstrasse 8 80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 January 2014 concerning maintenance of the European Patent No. 1190043 in amended form.**

Composition of the Board:

Chairman	B. Stolz
Members:	D. Pilat
	J. Geschwind

Summary of Facts and Submissions

I. European patent No. 1 190 043 is based on European patent application No. 00946953.7 (published as International patent application WO 01/00810; hereinafter "the patent application") and was opposed on the grounds of Articles 100(a), (b) and (c) EPC. The opposition division considered the main request to insufficiently disclose the claimed subject matter (Article 100(b) EPC) and auxiliary requests 1 to 6 to contravene Article 123(2) EPC, while auxiliary request 7 and the description adapted thereto were held to comply with the requirements of the EPC.

II. Both the patent proprietor (appellant I) and opponent 2 (appellant II) lodged an appeal against the decision of the opposition division. Both parties requested oral proceedings as an auxiliary measure. Appellant I filed a main request and auxiliary claim requests I to IV.

III. The parties replied to their respective statement of grounds of appeal. Appellant I filed an "auxiliary description request".

IV. The parties were summoned to oral proceedings. In a communication pursuant to Article 17(1) RPBA, the parties were informed of the board's provisional, non-binding opinion on some of the legal and substantive matters of the case.

V. In reply to the board's communication, appellant I, with a letter dated 6 September 2019, without making any substantive submissions, informed the board that it withdrew its request for oral proceedings and was not going to attend the oral proceedings.

The respondent (Opponent 1) with a letter dated 14 August 2019 withdrew its opposition.

VI. Oral proceedings were held on 2 October 2019 in the presence of the appellant II only.

VII. Claim 1 of the main request reads as follows:

> "1. An isolated nucleic acid molecule comprising a first nucleic acid molecule encoding a polypeptide having a glycoprotein VI (GPVI) activity, which activity is binding to collagen, wherein the first nucleic acid molecule comprises a nucleic acid molecule which encodes an extracellular domain of GPVI wherein the first nucleic acid molecule is selected from (1) a nucleic acid molecule encoding the amino acid sequence of SEQ ID. No. 9 and (2) a nucleic acid molecule encoding an amino acid sequence at least 85% identical to SEQ ID. No. 9 and further comprising a second nucleic acid molecule encoding a heterologous polypeptide operatively linked to the first nucleic acid molecule."
>
> "6. A fusion protein comprising a first polypeptide having a glycoprotein VI (GPVI) activity, which activity is binding to collagen, wherein the first polypeptide comprises an extracellular domain of GPVI, and further comprising a second polypeptide with a heterologous amino acid sequence, wherein the first polypeptide comprises the amino acid sequence of SEQ. ID. NO. 9 or an amino acid sequence at least 85% identical to SEQ. ID. NO. 9."

Independent claims 12 to 16 relate to methods and products for use as a pharmaceutical referring either

directly or indirectly to the subject-matter of claims 1 or 6. The dependent claims define embodiments thereof.

VIII. Appellant I's submissions, insofar as relevant to the present decision, may be summarized as follows:

Article 123(2) EPC

Main description request

The patent application disclosed fusion proteins of claim 6 and also "variants" and "derivatives" of TANGO 268 proteins. Contrary to appellant II's interpretation, a skilled person would not have replaced each occurrence of the term “polypeptides of the invention" and "proteins of the invention" by its definition as such a replacement resulted in odd combinations, even if the deleted definition was used, like variants of variants (see page 83, lines 33 of the patent application). In the light of the patent application as a whole, the skilled person read and defined the term "polypeptide of the invention" to generically relate to TANGO268 proteins, fragments derivatives and variants. For these reasons, the deletion of an original definition of the “polypeptides of the invention" or "proteins of the invention" did not affect the overall content of the patent's disclosure when compared to the patent application's disclosure and accordingly did not contravene Article 123(2) EPC.

Auxiliary description request

The auxiliary description request reinstating the definition assigned to the "polypeptide of the

invention" in the specification complied with Article 123(2) EPC. Besides, to avoid any confusion with what was the invention according to the disclosure of the patent, each occurrence of the word "invention" was replaced by the word "disclosure" in the description. These amendments remedied the alleged deficiency raised under Article 123(2) EPC by appellant II and complied with Rule 80 EPC.

IX. Appellant II's submissions, insofar as relevant to the present decision, may be summarized as follows:

Article 123(2) EPC

Main description request

The deletion of the definition of the "polypeptides of the invention" or "proteins of the inventions" on page 4, lines 11 to 15, of the patent resulted in the skilled person being presented with information which was not directly and unambiguously derivable from the patent application. Both expressions had to be interpreted in the light of the understanding of a skilled person reading the patent specification, which meant that all the embodiments in the description referring to these terms were held to refer to the fusion protein of claim 6 comprising yet a further heterologous sequence, as this was the only protein or polypeptide in the patent (i.e. subject-matter) that could be identified and designated, pursuant to Rule 43(1) EPC, to be of the invention. It followed that embodiments of the specification such as, for example, antibodies specifically binding a "polypeptide of the invention" or pharmaceutical compositions comprising a "polypeptide of the invention" had to refer to a fusion protein of claim 6. Finally, there was no direct and

unambiguous basis in the patent application for a combination of the specific fusion protein defined in claim 6 with the generic embodiments described in the specification. The description was therefore amended to extend beyond the content of the patent application in breach of Article 123(2) EPC.

Since the definition of a "nucleic acid of the invention" on page 4, lines 11 to 15, of the patent application was deleted in the patent specification, the meaning imparted to both terms, "polypeptides or proteins of the invention" and the term "nucleic acids of the invention", was modified.
The argument raised under Article 123(2) EPC against the term "polypeptide of the invention" was applicable to the term "nucleic acid of the invention" as the definition on page 4, lines 11 to 15, of the patent application was deleted. The term "nucleic acid molecules encoding the polypeptides or proteins of the invention" referring to said polypeptide of the invention was modified too.

Auxiliary description request

The amended description pages reintroducing inter alia the deleted definition of the "polypeptide of the invention" in the specification, filed with appellant I's letter of 19 September 2014, were inadmissible in view of the cut-off effect described in decision T 1149/97. The proposed amendments did not overcome the objection raised under Article 123(2) EPC, they contravened further provisions of the EPC, e.g. lack of clarity, and not all of them were occasioned by a ground of opposition under Article 100 EPC, as stipulated by Rule 80 EPC.

X. Appellant I requested the decision under appeal to be set aside and the patent to be maintained on the basis of the main request or alternatively based on one of auxiliary requests I to IV in combination with either the main description request or alternatively with the auxiliary description request.

XI. Appellant II requested the decision under appeal to be set aside and the patent to be revoked. He requested furthermore that neither auxiliary requests I to III nor the amended description filed by appellant I with letter of 19 September 2014 be admitted into the proceedings. As an auxiliary measure, in case the patent was maintained, it requested that a question relating to a point of law of fundamental importance be referred to the Enlarged Board of Appeal.

Reasons for the Decision

Main request

1. The duly summoned appellant I did not attend the oral proceedings, which in accordance with Rule 115(2) EPC and Article 15(3) RPBA took place in its absence. By its decision not to attend the oral proceedings and not to file substantive arguments in reply to the issues raised in the board's communication, appellant I has waived the opportunity to comment on the board's provisional opinion, either in writing or at oral proceedings, although this opinion was partially to appellant I's disadvantage. According to Article 15(3) RPBA, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying on its written case.

2. The description of the patent specification was amended by the patent proprietor during examination proceedings.

3. This case turns on the question of whether or not the amendments to the description performed before grant of the patent created subject matter extending beyond the content of the patent application as filed. This question is independent of the question whether any of the amended claim requests submitted in appeal proceedings meets the requirements of the EPC and if so whether amendments to the claim requests would make further amendments to the description necessary.

Article 123(2) EPC

Description

4. Appellant II submitted that the deletion from the patent specification of the definition given on page 4, lines 11 to 15, of the patent application of the terms "polypeptides of the invention" and "proteins of the inventions" resulted in the skilled person being presented with technical information which was not directly and unambiguously derivable from the patent application.

Since the definition of a "nucleic acid of the invention" on page 4, lines 11 to 15, of the patent application as originally filed was also deleted in the patent specification, the meaning of this term was also modified.

5. Appellant I asserted that the original definitions of the terms still applied. Otherwise, the patent defined

embodiments of the invention characterized by odd combinations of technical elements.

6. For the board, the issue to be assessed with regard to Article 123(2) EPC is whether the removal of the original definitions altered the meaning of the terms polypeptide or nucleic acid of the invention used throughout the description of the granted patent. And if so, whether any of the paragraphs referring to a "polypeptide of the invention" or a "nucleic acid of the invention" defines new subject-matter going beyond the content of the patent application.

6.1 The description on page 4, lines 11 to 15, of the patent application read as follows:

> "The TANGO 268 proteins, fragments, derivatives, and variants thereof are collectively referred to herein as "polypeptides of the invention" or "proteins of the invention." Nucleic acid molecules encoding the polypeptides or proteins of the invention are collectively referred to as "nucleic acids of the invention."

The term "Tango 268" is an alternative designation for glycoprotein VI or GPVI mentioned in the claims.

6.2 The definition of the term "polypeptides of the invention" used in the patent application was broad and unrestricted in scope. Since the original definition of this term was removed from the description of the granted patent and no other passage defining the meaning of the term directly and unambiguously was provided, there is no longer any basis in the patent specification for interpreting it as referring to TANGO268 proteins, fragments, derivatives and variants,

as proposed by appellant I. Thus, a skilled person reading the patent specification, especially the paragraphs describing embodiments referring to a "polypeptide of the invention", has to look for a definition of this term in the remaining parts of the patent. None of the paragraphs referring to "derivatives" and "variants" of the protein or polypeptide of the invention provide any guidance in this respect (see for instance paragraphs [0038], [0287] to [0289], [0335] of the granted patent). For this reason, the skilled person considers the claimed fusion protein as the sole identifiable polypeptide of the invention, in accordance with Rule 43(1) EPC, and construes the embodiments of the specification referring to a polypeptide of the invention to refer to it. This view is supported by the fact that a further embodiment of the invention (claim 1) is a nucleic acid molecule encoding the fusion protein of claim 6 (see paragraph [0011] of the patent).

6.3 Interpreting the term "polypeptide of the invention" in this way leads however to the disclosure of combinations of selected features which were not directly and unambiguously disclosed in the patent application.

6.4 For instance, paragraph [0280] of the granted patent indicates that the invention also provides a fusion or chimeric protein which "comprises all or part (...) of a polypeptide of the invention operably linked to a heterologous polypeptide (*i.e.* a polypeptide other than the same polypeptide of the invention)". A skilled person reading this passage derives directly and unambiguously that a polypeptide of the invention or a part thereof may be comprised in a fusion or chimeric protein which is not the fusion protein of claim 6, as

the polypeptide of the invention of said fusion protein is operably linked to a heterologous polypeptide. While it may not have been the intention of the drafters of the patent application, this interpretation is a direct consequence of the amendment of the description before grant of the patent. Moreover, while it may be an unusual way of defining the invention, this interpretation makes technical sense. It is however a fact that such a construct was not disclosed in the patent application as filed.

6.5 There is also no direct and unambiguous disclosure in the patent application of both, a pharmaceutical composition comprising a fusion protein of claim 6 and of antibodies reacting specifically with a fusion protein of claim 6, as described in paragraph [0049] of the patent specification.

6.6 The granted patent discloses therefore subject-matter which extends beyond the content of the application as filed and contravenes Article 123(2) EPC.

Admissibility of the appellant I's auxiliary description request

7. The board concurs with appellant I that the proposed reintroduction into the description of a definition of the "polypeptides of the invention" intends to overcome an objection under Article 123(2) EPC raised by appellant II.

7.1 The amendments proposed on pages 1 to 14 and 69 to 147 submitted by appellant I include on page 4, lines 11 to 15, a definition similar to the original definition of the "polypeptides of the invention" which had been deleted before grant. The definition differs however

from the original definition in that "polypeptides of the invention" was replaced by "polypeptides of the disclosure". The remaining amendments concern in the vast majority of the cases the replacement of the words "invention" or "described herein" by the words "disclosure" and "of the disclosure", respectively.

7.2 The admissibility of amendments to the patent in opposition/appeal proceedings is subject to the limitations laid down in Rule 80 EPC, which require the amendments to be occasioned by a ground for opposition under Article 100 EPC. Non-compliance with the restrictions imposed by Rule 80 EPC renders any amended description or amended claim request inadmissible if it contains amendments going beyond what is appropriate and necessary in order to overcome objections raised under Article 100 EPC (see decision T 1149/97 item 6.1.9 second paragraph).

8. In the board's view, some of the proposed amendments are not occasioned by a ground for opposition.

8.1 For example, paragraph [0018] of the granted patent read "[t]he present disclosure includes nucleic acid molecules ... wherein said nucleic acid molecules encode polypeptides or proteins that exhibit at least one structural and/or functional feature of a polypeptide described herein". Appellant I proposes now to amend the last line of this paragraph to read "... that exhibit at least one structural and/or functional feature of a polypeptide **of the disclosure**" (emphasis added) (see page 5, third paragraph, of the description filed with letter dated 19 September 2014).

8.2 Neither the term "described herein" nor the use of this term in paragraph [0018] of the specification was

objected to by the appellant II under Article 123(2) EPC, and the board fails to see any reason how its introduction before grant could have extended the content of the patent beyond the content of the application as filed. Appellant I did not provide any explanation in this respect either. The proposed amendment is thus not occasioned by a ground for opposition as required by Rule 80 EPC.

8.3 The same conclusion applies to the proposed replacement of the term "described herein" by the term "of the disclosure" in paragraphs [0023], [0026], [0034], [0037], [0041], [0042], [0043], [0058], [0060], [0061], [0241], [0243], [0316], [0349], [0354], [0410], [0412] to [0420], [0429], [0430], [0434], [0436], [0437], [0451], [0452] and [0454] of the granted patent (see page 6, lines 6 and 24; page 7, lines 27-33; page 8, lines 15-25; page 9 lines 13-19 and lines 20-30 and lines 31-32; page 13, lines 12-17; page 14, lines 6-14 and lines 15-21; page 69 line 36 to page 70 line 9; page 70 lines 18-25; page 96, lines 11-16; page 16, line 33 to page 107 line 14; page 108, lines 21-26; page 124, line 21 to page 125, line 7; page 125, line 16 to page 129, line 6; page 132 lines 1-14; page 133, lines 16-31; page 134 line 12 to page 135 line 8; page 139 lines 9-22; and page 140, lines 7-23 respectively, of the amended description filed with letter dated 19 September 2014).

For the same reason as developed for paragraph [0018] above, none of these amendments of the auxiliary description request are occasioned by a ground for opposition pursuant to Article 100 EPC.

8.4 Further proposed amendments concern the replacement of the term "antibody of the invention" by "antibody of

the disclosure", for example, in paragraphs [0297] and [0302] (see page 88, lines 21-33; and page 90, lines 10-20), or the replacement of the term "detection method of the invention" by "detection method of the disclosure" in paragraph [0427] (see page 131, lines 7-29 of the description filed with letter dated 19 September 2014).
The antibodies of the invention... ([0297]), the [h]ybridoma cells producing a monoclonal antibody of the invention... ([0302]), and the detection method of the invention ([0427]) were described in the patent specification as belonging to the invention although they are not claimed.

A possible inconsistency between the definition of the invention in the description and the claims leads at most to a lack of clarity (Article 84 EPC), which is however not a ground for opposition pursuant to Article 100 EPC.

Thus, the proposed amendments to the description in paragraphs [0297], [0302] and [0427] are inadmissible under Rule 80 EPC.

8.5 A further example of a proposed amendment not occasioned by a ground for opposition concerns the replacement of the term "The disclosure also provides for" by "The disclosure also includes" in paragraph [0422] of the patent (see page 129, lines 11 to 24 of the description filed with letter dated 19 September 2014). The reasons are the same as set out for paragraph [0018] (see point 8.2 above).

9. Since the auxiliary description request proposes many amendments not occasioned by a ground for opposition, it is not admitted into the proceedings.

10. Given that the main description request contravenes Article 123(2) EPC and the auxiliary description request is not admitted into the proceedings, there are no valid description requests on the basis of which the patent can be maintained.

11. In view of the above, there is no need to discuss the claim requests submitted with the statement of grounds of appeal in substance.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

L. Malécot-Grob B. Stolz

Decision electronically authenticated